DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 11, 2014

Q Core Medical Ltd.
C/O Rhona Shanker
Director, Regulatory Consulting
Z&B Enterprises, Inc.
12154 Darnestown Road, #236
GAITHERSBURG, MD 20878

Re: K141389
Trade/Device Name: Sapphire Infusion Pump
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN, FPA
Dated: November 12, 2014
Received: November 13, 2014

Dear Ms. Shanker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

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Erin I. Keith, M.S.
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141389

Device Name
Sapphire Infusion Pump

Indications for Use *(Describe)*
The Q Core Sapphire infusion pump is intended for the controlled delivery through intravascular, subcutaneous, intra-arterial and epidural routes. The pump is designed to deliver saline, Total Parenteral Nutrition (TPN), lipids, IV medication, epidural medication, blood and blood products.

The Sapphire pump includes the following infusion modes for all intended uses: Continuous, Intermittent, TPN, PCA, Multi-step, and Epidural.

The pump is intended to be used by both licensed health care professionals in a clinical environment, and home users in an ambulatory environment and in pre-hospital medical ground transportation.

The dedicated Q Core administration sets for the Sapphire pump are intended for single-patient use and single-use only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary K141389

Owner/Submitter	Q Core Medical Ltd. 29 Yad Haruzim St. Netanya 4250529 ISRAEL Ph: +972-73-2388888 Fax: +972-73-2388800
Contact Person	Rhona Shanker FDA Regulatory Consultant to Q Core Medical Ltd Ph: 301251-9570 Fax: 301-251-9571
Date Issued	15 May 2014
Trade Name	Sapphire Infusion Pump
Common Name	Infusion pump
Classification Name	Infusion Pump 21 CFR 880.5725 Intravascular administration set 21 CFR 880.5440 Product Codes: FRN - Infusion pump FPA - Administration Sets Class II
Predicate Device Infusion Pump	(K123049) Sapphire Infusion Pump (K042081)Plum A+® Infusion System with Hospira MedNet ™ Software
Administration Sets	Q Core Administration Sets cleared under K123049

Device Description

The enhanced Sapphire Infusion Pump with and without the WiFi capability is the result of modifications to the FDA cleared Sapphire Infusion pump (K123049). The modifications are the addition of WiFi to allow the pump to communicate wirelessly with compatible systems and additional Software enhancements. There are no changes to the basic infusion pump technology.

The Q Core Sapphire infusion pump is a single-channel, volumetric infusion pump that is intended for controlled delivery through intravascular, subcutaneous, intra-arterial and epidural routes. It is designed to deliver saline, Total Parenteral Nutrition (TPN), lipids, IV medication, epidural medication, blood and blood products and includes the following infusion modes for all intended uses: Continuous, Intermittent, TPN, PCA, Multi-step, and Epidural. The pump has alarms for occlusions, air in the line, administration set installment issues, and internal battery issues. The Pump includes software and is powered by an external power source or by an internal battery. It is intended to be used by both licensed health care professionals in the clinical environment, and home users in an ambulatory environment. The Sapphire pump is designed to follow the patient through the various care areas, and is suitable for use in the different settings.

The dedicated Q Core Administration Sets for the Sapphire infusion pump are provided sterile and are for single- use and single-patient use only. Components from the previously cleared administration sets were used to make sets with new configurations, all within the parameters (e.g. length, diameters, materials) of the sets cleared with the Sapphire Infusion Pump. These new configurations are substantially equivalent to the administration sets that were cleared under K123049, having identical indications for use and technological characteristics.

Indications for Use

The Q Core Sapphire infusion pump is intended for the controlled delivery through intravascular, subcutaneous, intra-arterial and epidural routes. The pump is designed to deliver saline, Total Parenteral Nutrition (TPN), lipids, IV medication, epidural medication, blood and blood products.

The Sapphire pump includes the following infusion modes for all intended uses: Continuous, Intermittent, TPN, PCA, Multi-step, and Epidural.

The pump is intended to be used by both licensed health care professionals in a clinical environment, and home users in an ambulatory environment and in pre-hospital medical ground transportation.

The dedicated Q Core administration sets for the Sapphire pump are intended for single-patient use and single-use only.

These are the same indications for use as the predicate Sapphire infusion pump.

Technological Characteristics

The enhanced Sapphire Infusion Pump with and without the WiFi functionality is the same as the FDA cleared Sapphire Infusion pump (K123049) with the addition of the WiFi function. The

addition of the WiFi function allows the pump to communicate wirelessly with compatible systems. There are no changes to the basic infusion pump technology.

The enhanced Sapphire infusion pump with and without WiFi functionality is substantially equivalent to the predicate devices in the following respects:

1. All pumps are volumetric and software controlled.
2. All pumps are indicated for the controlled delivery of programmed doses of saline, TPN, lipids, IV medication, epidural medication at selected rates and can be used in the hospital and out-of-hospital (home and pre-hospital) environments.
3. The Sapphire pump has six delivery modes: Continuous, Intermittent, Multi-step, PCA, TPN, and Epidural.
4. The pump is substantially equivalent to the Plum A+® Infusion System with Hospira MedNet ™ Software (K042081) with respect to the WiFi function.
5. The proposed and predicate Sapphire Infusion pumps have the same safety features to prevent free flow, alarms for the detection of upstream and downstream occlusions, low battery, end of infusion, and pump failure, and authorization levels to prevent misuse.

The new Q Core Administration Sets configurations to be used with the Sapphire Infusion Pump are substantially equivalent to those cleared under K123049 in the following respects:

1. All sets are dedicated for use with Q Core infusion pumps.
2. All sets are indicated for intravenous infusion.
3. All sets can be used only by or under the order of a licensed medical practitioner.
4. All sets consist of standard, conventional components such as Luer locks, PVC tubing, Y-connector, tubing clamp.
5. All sets use materials with the same characteristics (biocompatible, non-DEHP, latex free).
6. All sets have the same means to protect against free flow (cassette with an Anti-Free Flow Valve [AFFV]).
7. All sets are provided sterile, non-pyrogenic, intended for single patient use and single use.
8. All sets are intended for either hospital or home use.

Pre-Clinical Testing

Preclinical testing included in the submission to demonstrate that the enhanced Sapphire Infusion Pump is safe and performs as intended involved the following:

Electrical Safety per IEC 60601-1
EMC testing per IEC 60601-1-2

Software Verification and Validation per the FDA *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* dated May 11, 2005
Human Factors testing
FCC testing

Testing of the Administration Sets involved:
Shelf life

Conclusion

The enhanced Sapphire Infusion Pump with and without the WiFi functionality is substantially equivalent to the Sapphire Infusion Pump (K123049) (primary predicate) with respect to the indications for use, the basic infusion pump hardware or mechanism used to control delivery of the infusion, the delivery modes and safety features. The significant modification is the addition of WiFi to allow the pump to communicate wirelessly with compatible systems. The Sapphire is also substantially equivalent to the Plum A+® Infusion System with Hospira MedNet TM Software (K042081) in that they both have the WiFi function.

The new Q Core Administration Sets configurations that are to be used with the Sapphire Infusion Pump are substantially equivalent to those cleared under K123049.

In summary, the enhanced Sapphire Infusion Pump with and without WiFi functionality and its dedicated Administration Sets are substantially equivalent to its predicates with respect to indications for use, target populations, types of infusions, delivery modes, technological characteristics and safety features.